DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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February 8, 2015

OLYMPUS MEDICAL SYSTEMS CORP.
% Daphney Germain-Kolawole
Regulatory Affairs Project Manager
Olympus Corporation of the Americas
3500 Corporate Parkway, PO Box 610
Center Valley, PA 18034-0610

Re: K142680
Trade/Device Name: OLYMPUS SMALL INTESTINAL CAPSULE ENDOSCOPE SYSTEM
Regulation Number: 21 CFR§ 876.1300
Regulation Name: Ingestible telemetric gastrointestinal capsule imaging system
Regulatory Class: II
Product Code: NEZ
Dated (Date on orig SE ltr): November 17, 2014
Received (Date on orig SE ltr): November 18, 2014

Dear Daphney Germain-Kolawole,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K142680

Device Name
OLYMPUS SMALL INTESTINAL CAPSULE ENDOSCOPE SYSTEM

Indications for Use *(Describe)*
The OLYMPUS SMALL INTESTINAL CAPSULE ENDOSCOPE SYSTEM is intended for visualization of the small intestine mucosa. The Red Color Detection Function is intended to mark frames of the video suspected of containing blood or red areas.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) SUMMARY
OLYMPUS SMALL INTESTINAL CAPSULE ENDOSCOPE SYSTEM

September 18, 2014

I. General Information

- Applicant: OLYMPUS MEDICAL SYSTEMS CORP.
  2951 Ishikawa-cho, Hachioji-shi, Tokyo, Japan 192-8507
  Establishment Registration No: 8010047

- Official Correspondent: Daphney Germain-Kolawole
  Regulatory Affairs Project Manager
  Olympus Corporation of the Americas
  3500 Corporate Parkway
  PO Box 610
  Center Valley, PA 18034-0610, USA
  Phone: 484-896-5691
  FAX: 484-896-7128
  Email: daphney.germain-kolawole@olympus.com

- Manufacturer: OLYMPUS MEDICAL SYSTEMS CORP.
  HINODE PLANT
  34-3 Hirai, Hinode-machi, Nishitama-Gun, Tokyo, 190-0182, Japan
  Establishment Registration Number: 3003637092

II. Device Identification

- Device Trade Name: OLYMPUS SMALL INTESTINAL CAPSULE ENDOSCOPE SYSTEM
- Common Name: Capsule Imaging System
- Regulation Number: 876.1300
- Regulation Name: Ingestible telemetric gastrointestinal capsule imaging system
- Regulatory Class: II (Special Controls)
- Classification Panel: Gastroenterology and urology
- Product Code: NEZ

III. Predicate Device Information

Model name	Applicant	510(k) No.
OLYMPUS CAPSULE ENDOSCOPE SYSTEM	OLYMPUS MEDICAL SYSTEMS CORP.	K123421

IV. Device Description

OLYMPUS SMALL INTESTINAL CAPSULE ENDOSCOPE SYSTEM is a capsule imaging system used for visualization of the small intestine mucosa. This system consists of a capsule endoscope which captures images and transmits the data, an antenna unit and a recorder which are secured around the patient and receive data from the capsule, workstation software which downloads the image data from the recorder and processes images for visualization.

The new workstation software, MAJ-2188 ENDOCAPSULE SOFTWARE 10 and MAJ-2189 ENDOCAPSULE SOFTWARE 10 LIGHT, are the subjects of this submission.

V. Indications for Use

The OLYMPUS SMALL INTESTINAL CAPSULE ENDOSCOPE SYSTEM is intended for visualization of the small intestine mucosa. The Red Color Detection Function is intended to mark frames of the video suspected of containing blood or red areas.

VI. Comparison of Technological Characteristics

Compared to the legally marketed, predicate devices, the subject workstation software is reconstructed to improve operability. Technological characteristics of the subject device are identical or similar to the predicate device. A detailed comparison of the subject devices with the predicate devices is provided in the premarket notification.

VII. Summary of non-clinical testing

- Bench testing were performed to support technical changes.
- Risk analysis was carried out in accordance with established in-house acceptance criteria based on ISO 14971:2007. The design verification tests and their acceptance criteria were identified and performed as a result of this risk analysis assessment.
- The software validation activities were performed in accordance with the FDA Guidance, “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.” The device software is considered a Moderate Level of Concern.
- The following standards have been applied to the subject devices:

  - ISO 14971

VIII. Conclusion

When compared to the predicate device, the MAJ-2188 and the MAJ-2189 do not incorporate any significant changes in intended use, method of operation, or design that could affect the safety or effectiveness of the device.